10 December 2014

Scancell Holdings Plc

Interim Results for the six months ended 31 October 2014

SCIB1 continues to generate highly encouraging survival data; Modi-1 vaccine on track for 2016 entry into clinic

Scancell Holdings plc, ('Scancell' or the 'Company') the developer of novel immunotherapies for the treatment of cancer, announces its interim results for the six months ended 31 October 2014.

Highlights:

- Data from the on-going Phase 1/2 clinical trial in patients with Stage III/IV melanoma treated with the SCIB1 ImmunoBody® shows highly encouraging survival times in both Part 1 and Part 2 patient groups
- Pre-clinical data demonstrates that a combination of SCIB1 and checkpoint inhibition (PD-1 blockade) produced enhanced tumour destruction and longer survival times than when either treatment was used alone, supporting use of the combination for later stage disease
- Adjuvant melanoma* represents a significant new market opportunity for SCIB1
- SCIB2 vaccine ready for further pre-clinical development as a potential immunotherapy for any tumour expressing the NY-ESO-1 antigen
- Patent granted in the US for Scancell's DNA ImmunoBody® platform technology, following the grant of counterparts in Australia, China and Japan
- Modi-1, lead vaccine from Moditope® platform, is on schedule for clinical trials in 2016
- Two new Moditope® protein targets identified
- Loss for the six month period of £1,339,915 (2013: loss: £1,187,574)
- Group cash balance at 31 October 2014 was £4,302,052 (30 April 2014: £5,566,234)

Richard Goodfellow, Joint CEO of Scancell, said: *"We are delighted that our lead ImmunoBody®, SCIB1, continues to show the potential to extend the lives of melanoma patients without serious side effects. This encouraging data makes us increasingly optimistic about the clinical value of SCIB1 as monotherapy, especially in the adjuvant setting, a huge and relatively untapped market. Furthermore, the increased survival times when SCIB1 was combined with PD-1 blockade in pre-clinical studies gives us confidence that SCIB1 also has significant potential in combination with checkpoint inhibitors for late stage disease.*

"Our Moditope® platform is progressing well with Modi-1 expected to start clinical trials in 2016. Two additional Moditope® protein targets have also now been identified. The market opportunity for our two innovative technology platforms, ImmunoBody® and Moditope®, is significant and we remain committed to evaluating all available options for the realisation of shareholder value."

-ENDS-

*Patients without measurable disease following surgery but where there remains a high risk of relapse

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms.

Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma and is being evaluated in a Phase 1/2 clinical trial. Data from the trial demonstrate that SCIB1, when used as monotherapy, has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system: the helper cell system where inflammation is stimulated at the tumour site and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Pre-clinical data on a combination of SCIB1 and checkpoint inhibition (blockade of the PD-1 immune checkpoint pathway) has shown enhanced tumour destruction and significantly longer survival times than when either treatment was used alone.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4+ T cells that destroy tumours without toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.

CHAIRMAN'S STATEMENT

I am pleased to report the Company's interim results for the six month period ended 31 October 2014.

During this period Scancell continued to make progress with the SCIB1 Phase 1/2 clinical trial in melanoma. The encouraging survival and safety data from the trial suggest that SCIB1 has the potential to become the first effective adjuvant therapy for melanoma, addressing a significant unmet medical need. At the time of the most recent analysis in October 2014, all 16 patients with fully resected disease were still alive with a median survival of 26 months after starting treatment and only four had shown disease progression.

We also announced that pre-clinical studies using a combination of SCIB1 and PD-1 blockade showed enhanced tumour destruction and significantly longer survival times than when either treatment was used alone. This strongly supports the hypothesis that stimulating the immune system with SCIB-1 whilst simultaneously taking off the immunological brakes with the checkpoint inhibitors could be a very attractive option for the treatment of late stage disease. The funds raised in the last financial year have also allowed the Company to further develop the Moditope® platform. The first Moditope® development candidate, Modi-1, targeting vimentin, is on schedule to enter clinical trials in 2016. Two new Moditope® protein targets, alpha-enolase and ING4, both of which play a role in many cancer related processes, have also been identified.

Financial

Profit and Loss Account

The Group made an overall operating loss for the six month period to 31 October 2014 of £1,560,813 (2013: loss of £1,306,556). The major reason for the increased loss in the period is additional expenditure on development which has been partially offset by a reduction in administration expenses.

Overall the loss for the six month period was £1,339,915 (2013: loss £1,187,574).

Balance Sheet

The cash at bank at 31 October 2014 was £4,302,052 (30 April 2014: £5,566,234) and net assets amounted to £7,784,216 (30 April 2014: £9,077,264).

ImmunoBody® platform

Scancell's ImmunoBody® immunotherapy platform enhances the uptake and presentation of cancer antigens to harness high avidity T cell responses that destroy tumours. Each ImmunoBody® vaccine can be designed to target a particular cancer in a highly specific manner, offering the potential for enhanced efficacy and safety compared with more conventional approaches. The platform has been validated both in animals and in the clinic with the Company's first cancer vaccine, SCIB1, and many opportunities also exist for the development of a pipeline of ImmunoBody® vaccines, both for cancer and chronic infectious diseases.

SCIB1 melanoma vaccine

The on-going Phase 1/2 clinical trial in patients with Stage III/IV melanoma treated with SCIB1 continues to provide further encouraging data. At the time of the most recent analysis and report on 13 October 2014, 32 patients had been treated with SCIB1, including seven at the higher 8mg dose and six patients were on long-term (greater than 6 months) treatment. Although recruitment of patients with advanced disease remains challenging due to competing clinical studies, it is expected that enrolment for the study will be completed during the second quarter of 2015. A new clinical centre has been established at the Royal Surrey County Hospital in Guildford to accelerate recruitment. SCIB1 continues to be a safe and well tolerated treatment with no withdrawals from the study due to adverse events.

Overall, only five of the 27 patients who received at least three doses of 2-8mg SCIB1 since commencement of the study in 2010 have died. Median survival time in Part 1 patients who received at least three treatments with the 2mg/4mg doses of SCIB1 was 34 months since study entry. This group of patients had 1-year, 2-year and 3-year survival rates of 100%, 67% and 50%, respectively. For the Part 1 8mg cohort of patients, who were recruited later, the median survival time was 13 months since study entry. The median survival time since initiating treatment with SCIB1, in Part 2 patients with resected disease (and receiving 4mg doses of SCIB1) was 25 months.

The results in patients with resected disease suggest that SCIB1 may have an important role to play as adjuvant therapy for melanoma, an important area of unmet medical need. These patients no longer have measurable disease (following surgery) and are generally quite well. However, they are at a high risk of recurrence and currently have very few, if any, effective treatment options. This represents a significant and as yet untapped market opportunity, including some 360,000 patients in the US alone, of whom around 45% have the MHC antigen HLA-A2 and are therefore suitable for SCIB1 treatment.

Scancell has previously shown that administration of SCIB1 alone induced potent tumour-specific T cell responses associated with increased T cell infiltration into the tumour and enhanced proliferation of T cells resulting in tumour rejection and long-term survival in 50% of animals. In our new study, checkpoint inhibition (blockade of the PD-1 immune checkpoint pathway), when used alone, resulted in tumour rejection and long-term survival in 55% of animals. However, the combination of PD-1 blockade with SCIB1 vaccination further enhanced T cell infiltration, resulting in tumour rejection and long-term survival in 85% of animals. These results highlight the potential benefits of combining SCIB1 with PD-1 blockade in the treatment of cancer. Any patients that progress following SCIB1 monotherapy, or indeed any patient with more advanced disease, may therefore benefit from the combination of SCIB1 with a checkpoint inhibitor.

SCIB2 vaccine

A second ImmunoBody® vaccine targeting the lung cancer antigen NY-ESO-1 (SCIB2) has been developed to the point at which the product is fully defined and ready for further pre-clinical development as a potential immunotherapy for any tumour that expresses the NY-ESO-1 antigen such as lung, oesophageal, gastric, ovarian and bladder cancers. During the past 12 months, research on other ImmunoBody® vaccines for prostate, liver and colorectal cancer has also further advanced.

In addition, Scancell has conducted proof of concept studies with ImmunoBody® constructs expressing antigens from influenza and Epstein Barr virus.

Patents

A patent for Scancell's DNA ImmunoBody® technology platform has been granted in the United States.

The patent is key for the protection of the Company's pipeline of ImmunoBody® vaccines and follows the grant of other patents in Australia, China and Japan.

Moditope® platform

Modi-1

Scancell's Moditope® immunotherapy platform is based on exploiting the normal immune response to stressed cells, which is largely mediated by CD4+ T cells, and harnessing this mechanism to eradicate cancer cells. Scancell's first target for Moditope® is vimentin – a major cytoskeletal protein found in mesenchymal cells (cells that can differentiate into different cell types). Many epithelial tumours switch from expression of cytokeratin to vimentin during metastasis in a process known as epithelial mesenchymal transition (EMT); this change in phenotype enables the cell to become mobile and metastasise to new locations in the body.

Scancell has now selected two modified vimentin peptides in which the arginine residues have been substituted by citrulline to form the basis of its first Moditope® development candidate, Modi-1. The inclusion of additional modified peptides from other Moditope® target proteins into Modi-1 is currently under review. Animal studies have shown that the two vimentin peptides stimulate potent anti-tumour responses and leads to significant improvements in survival, suggesting that the Modi-1 product could have outstanding potential as a novel immunotherapy. Immune response studies with cells isolated from cancer patients have confirmed that T cell responses were stimulated by both modified vimentin peptides.

Optimisation studies have identified the adjuvant, dose and administration route for testing Modi-1 in the first-in-man study. In animal studies, an aggressive tumour cell line confirmed that the two vimentin peptides eradicate tumour cells in a therapeutic, and therefore clinically relevant, setting. Remarkably, these responses were evident when tumours had reached a late stage of development.

Moditope® vaccines have the potential to treat a wide variety of cancers. Scancell is currently further evaluating the initial indications for the first clinical trial with Modi-1 in terms of clinical need and market opportunity and based upon the possible addition of other peptide targets into the product.

Scancell is considering options for conducting the initial Modi-1 study in both Europe and the US and is designing the development and regulatory strategy to allow for either approach. The development programme will include manufacture plus toxicology and stability testing of the final formulated product. This data will form the basis of a clinical trial application, which is anticipated to be ready for submission in the first half of 2016.

Additional targets

Having exemplified the Moditope® platform with modified vimentin peptides, Scancell has been expanding the platform to other citrullinated tumour proteins that could be incorporated into Modi-1 or developed into a pipeline of other multiple-cancer immunotherapeutics and has identified two further Moditope® protein targets, alpha-enolase and ING4.

Human alpha-enolase is a glycolytic enzyme that is overexpressed by lung, liver and other cancers. We have identified a citrullinated peptide within human alpha-enolase that induces a powerful and specific immune response and that elicits both increased survival and decreased tumour volume compared to control groups in animal models. Analysis of blood samples from donors has indicated that humans have a T cell repertoire that is able to recognise citrullinated alpha-enolase.

The tumour suppressor protein encoded by the ING4 gene plays a role in many cancer related processes. Two citrullinated peptides from human ING4 have been shown to induce specific T cell responses. Further studies are ongoing to evaluate the effect of these citrullinated peptides on tumour volume and survival. Both alpha-enolase and ING4 are believed to offer excellent prospects for future Moditope® immunotherapies.

Outlook

Cancer immunotherapy continues to emerge as one of the most exciting areas of pharmaceutical research and development. Scancell now has two innovative technology platforms, ImmunoBody® and Moditope® in this disease transforming field. The encouraging survival data on SCIB1, especially in patients with resected disease, offers an even greater market opportunity for SCIB1. Our ImmunoBody® platform continues to make good progress with a second vaccine target for lung cancer and the potential to take the platform into chronic infectious diseases. Modi-1 remains on track for start of first-in-man clinical trials in 2016. The identification of new targets suggests that Moditope® has significant potential as a platform for generating multiple cancer immunotherapeutics.

The market opportunity for SCIB1 and other ImmunoBody® vaccines for adjuvant disease combined with the novelty, potency and potential utility of Moditope® for the treatment of multiple cancers, is significant and is likely to be attractive to some of the many pharmaceutical and biotechnology companies committed to or considering investing in this rapidly developing field. The Company is in the process of engaging with a number of pharmaceutical and biotechnology companies with a view to accelerating the development of one or more of the Company's programmes. Whilst we are still focused on securing the sale of all or part of the

Company, the Board will consider all available options in line with their commitment to realise shareholder value.

David Evans
Chairman

Scancell Holdings plc
Consolidated Profit or Loss and Other Comprehensive Income Statement
for the six months to 31 October 2014

	Unaudited Six months 31/10/2014 £	Unaudited Six months 31/10/2013 £	Audited Year to 30/04/2014 £
Continuing operations			
Development expenses	(1,072,984)	(666,766)	(1,677,115)
Administrative expenses	(487,829)	(639,790)	(820,105)
OPERATING LOSS	(1,560,813)	(1,306,556)	(2,497,220)
Interest receivable and similar income	70,898	3,982	29,186
LOSS BEFORE TAXATION	(1,489,915)	(1,302,574)	(2,468,034)
Tax on loss on ordinary activities	150,000	115,000	245,080
LOSS FOR THE PERIOD	**(1,339,915)**	**(1,187,574)**	**(2,222,954)**
Attributable to:			
Equity holders of the parent company	**(1,339,915)**	**(1,187,574)**	**(2,222,954)**
EARNINGS PER ORDINARY SHARE (PENCE) Note 2			
Basic	(0.60)	(0.57)	(1.03)
Diluted	(0.60)	(0.57)	(1.03)

Scancell Holdings plc
Consolidated Statement of Changes in Equity
for the six month period to 31 October 2014

	Share capital	Share premium account	Share option reserve	Retained earnings	Total Equity
	£	£	£	£	£
	Unaudited	*Unaudited*	*Unaudited*	*Unaudited*	*Unaudited*
At 1 May 2014	224,951	16,036,276	522,358	(7,706,321)	9,077,264
(Loss) for the period				(1,339,915)	(1,339,915)
Share option costs			46,867		46,867
At 31 October 2014	224,951	16,036,276	569,225	(9,046,236)	7,784,216
At 1 May 2013	194,470	9,904,733	509,914	(5,516,972)	5,092,145
(Loss) for the period				(1,187,574)	(1,187,574)
Share issue (net of expenses)	28,889	6,061,481			6,090,370
Share option costs			11,378		11,378
At 31 October 2013	223,359	15,966,214	521,292	(6,704,546)	10,006,319
	Audited	*Audited*	*Audited*	*Audited*	*Audited*
At 1 May 2013	194,470	9,904,733	509,914	(5,516,972)	5,092,145
(Loss) for the year				(2,222,954)	(2,222,954)
Exercise of options	1,592	70,062	(33,605)	33,605	71,654
Share issue (net of expenses)	28,889	6,061,481			6,090,370
Share option costs			46,049		46,049
At 30 April 2014	224,951	16,036,276	522,358	(7,706,321)	9,077,264

Scancell Holdings plc
Consolidated Statement of Financial Position
as at 31 October 2014

	Unaudited	Unaudited	Audited
	31/10/2014	31/10/2013	30/04/2014
	£	£	£
ASSETS			
Non-current assets			
Plant and equipment	100,811	134,937	115,621
Goodwill	3,415,120	3,415,120	3,415,120
	3,515,931	3,550,057	3,530,741
Current assets			
Trade and other receivables	78,643	123,827	146,514
Income tax assets	396,652	367,000	371,366
Cash and cash equivalents	4,302,052	6,395,927	5,566,234
	4,777,347	6,886,754	6,084,114
TOTAL ASSETS	8,293,278	10,436,811	9,614,855
LIABILITIES			
Current liabilities			
Trade and other payables	(509,062)	(430,492)	(537,591)
TOTAL LIABILITIES	(509,062)	(430,492)	(537,591)
NET CURRENT ASSETS	4,268,285	6,456,262	5,546,523
NET ASSETS	7,784,216	10,006,319	9,077,264
TOTAL EQUITY			
Called up share capital	224,951	223,359	224,951
Share premium account	16,036,276	15,966,214	16,036,276
Share option reserve	569,225	521,292	522,358
Retained earnings	(9,046,236)	(6,704,546)	(7,706,321)
	7,784,216	10,006,319	9,077,264

Scancell Holdings plc
Consolidated Cash Flow Statement
for the six month period to 31 October 2014

	Unaudited Six months 31/10/2014 £	Unaudited Six months 31/10/2013 £	Audited Year to 30/04/2014 £
Cash flows from operating activities			
Operating (loss) for the period	(1,560,813)	(1,306,556)	(2,497,220)
Depreciation	14,810	16,457	38,962
Share based payment expense	46,867	11,378	46,049
Operating (loss) profit for the year before changes in working capital	(1,499,136)	(1,278,721)	(2,412,209)
(Increase)/decrease in trade and other receivables	67,871	(6,663)	(29,350)
(Decrease)/increase in trade and other payables	(28,529)	115,378	222,477
Cash generated from operations	(1,459,794)	(1,170,006)	(2,219,082)
Income taxes received	124,714	-	125,715
Net cash from operating activities	(1,335,080)	(1,170,006)	(2,093,367)
Cash flows from investing activities			
Asset acquisition	-	(19,738)	(22,930)
Finance income	70,898	3,982	29,186
Net cash used by investing activities	70,898	(15,756)	6,256
Cash flows from financing activities			
Proceeds from issue of share capital	-	6,500,000	6,571,654
Expenses of share issue	-	(409,631)	(409,629)
Net cash generated from financing activities	-	6,090,369	6,162,025
Net increase/(decrease) in cash and cash equivalents	(1,264,182)	4,904,607	4,074,914
Cash and cash equivalents at beginning of the year	5,566,234	1,491,320	1,491,320
Cash and cash equivalents at end of the period	4,302,052	6,395,927	5,566,234

Scancell Holdings plc
Notes to the Interim Financial Statements
for the period to 31 October 2014

1 Basis of preparation

This interim statement for the six month period to 31 October 2014 is unaudited and was approved by the Directors on 9 December 2014. The financial information contained in the interim report has been prepared in accordance with the accounting policies set out in the annual report and accounts for the year ended 30 April 2014.

The financial information contained in the interim report does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. The financial information for the full preceding year is based on the statutory accounts for the year ended 30 April 2014, upon which the auditors, Champion Accountants LLP, issued an unqualified audit opinion which did not contain any statement under section 498(2) or 498(3) of the Companies Act 2006. The audited statutory accounts for the year ended 30 April 2014 have been lodged with the Registrar of Companies.

As permitted, this interim report has been prepared in accordance with AIM Rule 18 and not in accordance with IAS 34 "Interim Financial Reporting" therefore it is not fully in compliance with IFRS as adopted by the European Union.

2 Earnings per share

Basic earnings per share, from continuing operations, is calculated by dividing the earnings attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year.

The calculations of earnings per share are based on the following losses and numbers of shares.

	Six months to 31/10/2014	Six months to 31/10/2013	Year ended 30/04/2014
Loss after taxation	(1,339,915)	(1,187,574)	(2,222,954)
Weighted average number of shares	224,950,683	208,677,135	216,700,004
Basic earnings per share	(0.60)p	(0.57)p	(1.03)p

At 31 October 2014 the Company had 224,950,683 Ordinary Shares of 0.1p in issue.

3 Taxation

Taxation for the six months ended 31 October 2014 is based on the effective rates of taxation which are estimated to apply for the year ended 30 April 2015.

4 Interim results

These results were approved by the Board of Directors on 9 December 2014. Copies of the interim report are available to the public from the Group's registered office and the Group's website, www.scancell.co.uk.